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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/930,026 | 08/14/2001 | Preeti Lal | PF-0502-1 DIV | 2308 |

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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | 5 |

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/930,026 | LAL ET AL. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 February 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,9-11 and 13-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 2, 9-11, 13-28* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2, 16 and 17, drawn to ubiquitin-conjugating enzyme homologs, classified in Class 530, subclasses 350.

II. Claims 9 and 11, drawn to nucleic acids encoding ubiquitin-conjugating enzyme homologs and methods of detecting said nucleic acids, classified in Class 435, subclass 6 and Class 536, subclass 23.5.

III. Claim 10, drawn to antibodies, classified in Class 530, subclass 387.1.

IV. Claims 13-15, drawn to methods for detecting nucleic acids, classified in Class 435, subclass 6.

V. Claim 18, drawn to a method of treatment with a protein, classified in Class 514, subclass 12.

VI. Claim 19, drawn to methods of screening for an agonist, classified in Class 435, subclass 4.

VII. Claim 20, drawn to an agonist, classified in Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the agonist).

VIII. Claim 21, drawn to methods of treatment with an agonist, classified in Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the agonist).

IX. Claim 22, drawn to methods of screening for an antagonist, classified in Class 435, subclass 4.

X. Claim 23, drawn to an antagonist, classified in Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the antagonist).

XI. Claim 24, drawn to methods of treatment with an antagonist, classified in Class 514, subclass 1 (further classification cannot be determined without additional information regarding the structure of the antagonist).

XII. Claim 25, drawn to methods to identify a compound that binds to a ubiquitin protein, classified in Class 435, subclass 7.1.

XIII. Claim 26, drawn to a method of screening for compounds that modulate the activity of a ubiquitin protein, classified in Class 435, subclass 4.

XIV. Claim 27, drawn to methods of screening for compounds that increase the expression of a ubiquitin nucleic acid, classified in Class 435, subclass 6.

XV. Claim 28, drawn to methods of assaying for the toxicity of a compound, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct in structure and physicochemical properties. Invention II is drawn to nucleic acids whereas invention I is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have

different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while proteins may be utilized in ligand binding assays or to generate antibodies. Synthesis of the proteins of invention I do not require the particular products of the nucleic acids of invention II since the proteins of invention I can be isolated from natural sources or chemically synthesized.

Inventions I and III are patentably distinct in structure in that the proteins of invention I have a different amino acid sequence as compared to the antibodies of invention III. Furthermore, the products of invention I and III are utilized in different methodologies, such that the proteins may be utilized in ligand binding assays and the antibodies may be used in therapeutic methods. Synthesis of the antibodies of invention III does not require the particular products of the proteins of invention I since the antibodies of invention III can be isolated from natural sources.

Inventions I and IV, inventions I and XIV and inventions I and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the proteins of invention I are not required to practice the nucleic acid detection methods of inventions IV, XIV and XV.

Inventions I and V, VI, VIII, IX, XI, XII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of invention I can be used in a materially different process, such as methods of generating antibodies.

Inventions I and VII, inventions I and X, inventions III and VII, inventions III and X, and inventions VII and X are patentably distinct in structure in that the proteins of invention I and antibodies of invention III each consist of a specific amino acid sequence, whereas the agonists and antagonists of inventions VII and X may comprise any type of biological molecule, including proteins of different amino acid sequence, carbohydrates, non-organic compounds, etc. Furthermore, the products of invention I, III, VII and X are utilized in different methodologies, such that the proteins and antibodies of inventions I and III may be utilized in ligand binding assays, whereas the agonists and antagonists of inventions IV and V may be used in therapeutic methods.

Inventions II and III, II and VII and II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the nucleic acids of invention II are not required to make or use the antibodies of invention III, the agonists of invention VII or the antagonists of invention X. Further, each of these inventions have different functions and have different physical and structural properties.

Inventions II and IV, inventions II and XIV and II and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of invention II can be used in a materially different process, such as therapeutic methods.

Inventions II and V, inventions II and VI, inventions II and VIII, inventions II and IX, inventions II and XI, inventions II and XII and inventions II and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the nucleic acids of invention II are not required to practice the methods of inventions V, VI, IX, XI, XII and XIII.

Inventions III and IV, inventions III and XIV and inventions III and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the nucleic acid detection methods of inventions IV, XIV and XV.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the protein methods of inventions VI.

Inventions III and VI, inventions III and VIII, inventions III and IX and inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the antibodies of invention III are not required to practice the agonist and antagonist methods of inventions VI, VIII, IX and XI.

Inventions III and XII and inventions III and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antibodies of invention III can be used in a materially different process, such as therapeutic methods.

Inventions IV, V, VI, VIII, IX, XI, XII, XIII, XIV and XV are each drawn to patentably distinct methods. The methods of each of the inventions involve performing different method steps, require the use of different reagents and have different objectives. The methods of

inventions IV, V, VI, VIII, IX, XI, XII, XIII, XIV and XV are distinct and unobvious over each other.

Inventions VI and VII and inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the agonists of invention VII can be used in a materially different process, depending on the composition of the agonists, such as for generating antibodies or for isolating factors which bind to the agonists.

Inventions VII and IX and VII and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the agonists of invention VII are not required to practice the methods of inventions IX and XI.

Inventions IX and X and inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the antagonists of invention X can be used in

a materially different process, depending on the composition of the antagonists, such as for generating antibodies or for isolating factors which bind to the antagonists.

Inventions X and VI and inventions X and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the antagonists of invention X are not required to practice the methods of inventions VI and VIII.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-XV require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

February 11, 2003

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER